DEPARTMENT OF THE AIR FORCE
59TH MEDICAL WING (AETC)
JOINT BASE SAN ANTONIO - LACKLAND TEXAS

31 MAR 2016

MEMORANDUM FOR 59 MDW/ST
ATTN: MAJ CUBBY L GARDNER

FROM: 59 MDW/SGVU

SUBJECT: Professional Presentation Approval

1. Your paper, entitled **Severe and Significant Variation in Overnight Heart Rate and Blood Oxygen Saturation in Patients with Heart Failure** presented at **Military Health System Research Symposium, Venue TBA, 15-18 August 2016** with MDWI 41-108, and has been assigned local file #**16143.**

2. Pertinent biographic information (name of author(s), title, etc.) has been entered into our computer file. Please advise us (by phone or mail) that your presentation was given. At that time, we will need the date (month, day and year) along with the location of your presentation. It is important to update this information so that we can provide quality support for you, your department, and the Medical Center commander. This information is used to document the scholarly activities of our professional staff and students, which is an essential component of Wilford Hall Ambulatory Surgical Center (WHASC) internship and residency programs.

3. Please know that if you are a Graduate Health Sciences Education student and your department has told you they cannot fund your publication, the 59th Clinical Research Division may pay for your basic journal publishing charges (to include costs for tables and black and white photos). We cannot pay for reprints. If you are 59 MDW staff member, we can forward your request for funds to the designated wing POC.

4. Congratulations, and thank you for your efforts and time. Your contributions are vital to the medical mission. We look forward to assisting you in your future publication/presentation efforts.

for LINDA STEEL-GOODWIN, Col, USAF, BSC
Director, Clinical Investigations & Research Support

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1. TO: CLINICAL RESEARCH	2. FROM: (Author's Name, Rank, Grade, Office Symbol)	3. GME/GHSE STUDENT:	4. PROTOCOL NUMBER:
	Cubby L. Gardner, Maj, O-4, 59MDW/ST	☐ YES ☒ NO	WRNMMC 400924-4

5. PROTOCOL TITLE: (**NOTE:** For each new release of medical research or technical information as a publication/presentation, a new 59 MDW Form 3039 must be submitted for review and approval.)

Assessment of electronic collection & visual display of ecologically valid clinical data in patients with heart failure

6. TITLE OF MATERIAL TO BE PUBLISHED OR PRESENTED:

Severe and Significant Variation in Overnight Heart Rate and Blood Oxygen Saturation in Patients with Heart Failure

7. FUNDING RECEIVED FOR THIS STUDY? ☒ YES ☐ NO FUNDING SOURCE: Intramural USUHS

8. DO YOU NEED FUNDING SUPPORT FOR PUBLICATION PURPOSES: ☐ YES ☒ NO

9. IS THIS MATERIAL CLASSIFIED? ☐ YES ☒ NO

10. IS THIS MATERIAL SUBJECT TO ANY LEGAL RESTRICTIONS FOR PUBLICATION OR PRESENTATION THROUGH A COLLABORATIVE RESEARCH AND DEVELOPMENT AGREEMENT (CRADA), MATERIAL TRANSFER AGREEMENT (MTA), INTELLECTUAL PROPERTY RIGHTS AGREEMENT ETC.?
☐ YES ☒ NO **NOTE:** If the answer is YES then attach a copy of the Agreement to the Publications/Presentations Request Form.

11. MATERIAL IS FOR: ☒ DOMESTIC RELEASE ☐ FOREIGN RELEASE
CHECK APPROPRIATE BOX OR BOXES FOR APPROVAL WITH THIS REQUEST. ATTACH COPY OF MATERIAL TO BE PUBLISHED/PRESENTED.

☐ 11a. PUBLICATION/JOURNAL (List intended publication/journal.)

☐ 11b. PUBLISHED ABSTRACT (List intended journal.)

☒ 11c. POSTER (To be demonstrated at meeting: name of meeting, city, state, and date of meeting.)
Military Health System Research Symposium, Venue TBA, 15-18 AUG 2016

☐ 11d. PLATFORM PRESENTATION (At civilian institutions: name of meeting, state, and date of meting.)

☐ 11e. OTHER (Describe: name of meeting, city, state, and date of meeting.)

12. EXPECTED DATE WHEN YOU WILL NEED THE CRD TO SUBMIT YOUR CLEARED PRESENTATION/PUBLICATION TO DTIC
NOTE: All publications/presentations are required to be placed in the Defense Technical Information Center (DTIC).

DATE
March 29, 2016

13. 59 MDW PRIMARY POINT OF CONTACT (Last Name, First Name, M.I., email)	14. DUTY PHONE/PAGER NUMBER
GARDNER, Cubby L,cubby.gardner.1@us.af.mil	292-6785

15. AUTHORSHIP AND CO-AUTHOR(S) List in the order they will appear in the manuscript.

LAST NAME, FIRST NAME AND M.I.	GRADE/RANK	SQUADRON/GROUP/OFFICE SYMBOL	INSTITUTION (If not 59 MDW)
a. Primary/Corresponding Author Cubby L. Gardner	Maj	59MDW/ST	
b. Harry B. Burke			USUHS
c.			
d.			
e.			
f.			

I CERTIFY ANY HUMAN OR ANIMAL RESEARCH RELATED STUDIES WERE APPROVED AND PERFORMED IN STRICT ACCORDANCE WITH 32 CFR 219, AFMAN 40-401_IP, AND 59 MDWI 41-108. I HAVE READ THE FINAL VERSION OF THE ATTACHED MATERIAL AND CERTIFY THAT IT IS AN ACCURATE MANUSCRIPT FOR PUBLICATION AND/OR PRESENTATION.

16. AUTHOR'S PRINTED NAME, RANK, GRADE	17. AUTHOR'S SIGNATURE	18. DATE
Cubby L. Gardner, Maj, O-4	GARDNER.CUBBY.L.1233125683	March 23, 2016

19. APPROVING AUTHORITY'S PRINTED NAME, RANK, TITLE	20. APPROVING AUTHORITY'S SIGNATURE	21. DATE
Killian, Jacqueline M, Lt Col, O-5	KILLIAN.JACQUELINE.M.1050091976	March 23, 2016

PROCESSING OF PROFESSIONAL MEDICAL RESEARCH/TECHNICAL PUBLICATIONS/PRESENTATIONS

1st ENDORSEMENT (59 MDW/SGVU Use Only)

TO: Clinical Research Division 59 MDW/CRD Contact 292-7141 for email instructions.	22. DATE RECEIVED 3/25/2016	23. ASSIGNED PROCESSING REQUEST FILE NUMBER 16143
24. DATE REVIEWED 25 Mar 2016		25. DATE FORWARDED TO 502 ISG/JAC

26. AUTHOR CONTACTED FOR RECOMMENDED OR NECESSARY CHANGES: ☒ NO ☐ YES If yes, give date. _____ ☐ N/A

27. COMMENTS ☒ APPROVED ☐ DISAPPROVED

The abstract and poster presentation are approved.

28. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	29. REVIEWER SIGNATURE	30. DATE
Rocky Calcote, PhD, Clinical Research Administrator	CALCOTE.ROCKY.D.1178245844	

2nd ENDORSEMENT (502 ISG/JAC Use Only)

31. DATE RECEIVED	32. DATE FORWARDED TO 59 MDW/PA
25 Mar 16	28 Mar 16

33. COMMENTS ☒ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

Both the proposed abstract and the proposed poster properly contain the required disclaimer, "The views expressed are those of the author and do not reflect the official views or policy of the Department of Defense or its Components."

34. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	35. REVIEWER SIGNATURE	36. DATE
M.E. Coon, O-4, USAF	COON.MARK.E.1252306044	28 Mar 16

3rd ENDORSEMENT (59 MDW/PA Use Only)

37. DATE RECEIVED	38. DATE FORWARDED TO 59 MDW/SGVU
March 29, 2016	March 31, 2016

39. COMMENTS ☒ APPROVED (In compliance with security and policy review directives.) ☐ DISAPPROVED

40. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	41. REVIEWER SIGNATURE	42. DATE
Christopher Carwile, TSgt/E-6, NCOIC, PA	CARWILE.CHRISTOPHER.STEWART.1280477229	March 31, 2016

4th ENDORSEMENT (59 MDW/SGVU Use Only)

43. DATE RECEIVED	44. SENIOR AUTHOR NOTIFIED BY PHONE OF APPROVAL OR DISAPPROVAL ☐ YES ☐ NO ☐ COULD NOT BE REACHED ☐ LEFT MESSAGE

45. COMMENTS ☐ APPROVED ☐ DISAPPROVED

46. PRINTED NAME, RANK/GRADE, TITLE OF REVIEWER	47. REVIEWER SIGNATURE	48. DATE

Severe and Significant Variation in Overnight Heart Rate and Blood Oxygen Saturation in Patients with Heart Failure

Cubby L. Gardner, FNP-C, PhD[1] Harry B. Burke, MD, PhD[2]

[1]59th Medial Wing Science & Technology Nursing Research Division, Joint Base San Antonio – Lackland, TX

[2]F. Edward Hébert School of Medicine, Uniformed Services University of the Health Sciences, Bethesda, MD

Introduction

Accurate between-visit information is essential to the management of patients with chronic disease, such as heart failure. Information provided by patients during interval history is often inaccurate and incomplete; yet, it is this information upon which clinician base treatment decisions. Moreover, short duration studies, as with polysomnography, are unable to capture night-to-night variability that patients experience. Patient-facing electronic devices are capable of collecting, storing and transmitting data that would be otherwise inaccessible. We hypothesize that patients with heart failure experience severe and significant night-to-night differences in blood oxygen saturation and heart rate.

Methods

We recruited 37 patients with heart failure during routine clinic visits. Patients were asked to wear a pulse oximeter and actigraph overnight for six nights, patients returned the equipment 7 days later. In addition to describing nocturnal blood oxygen saturation, heart rate and activity, we conducted one-way analysis of variance crossing blood oxygen saturation and heart rate across nights and constructed 3D plots of abnormal measures.

Results

The average age of the participants was 67.2 (SD, 12.6), 26 (70%) were male, 24 (65%) were African-American. In terms of NYHC: I, 11 (30%); II, 20 (54%); and III, 6 (16%). Two patients were prescribed nocturnal oxygen therapy, and eight patients were prescribed CPAP at night.

Across all patients, the mean oxygen saturation across all nights for all patients was 92.4% (SD, 3.5). There was low variation in oxygen saturation, mean coefficient of variability was 0.03 (SD, 0.01). The mean minimum oxygen saturation was 71% (SD, 11.5%) and the mean maximum oxygen saturation was 99% (SD, 1.4%). Approximately 41%, (15 of 37) patients experienced oxygen saturations below 70%. Furthermore, approximately 16% (6 of 37) patients experienced oxygen saturations below 60%.

Results

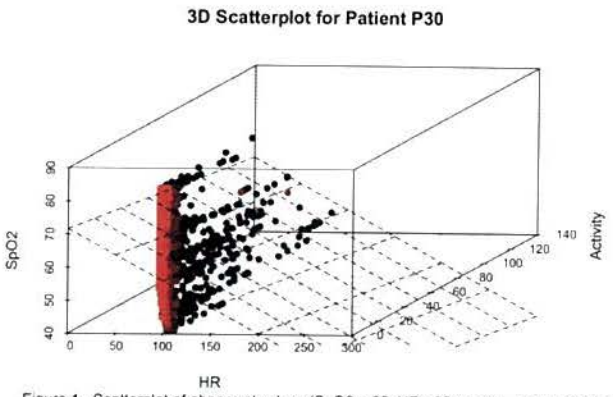
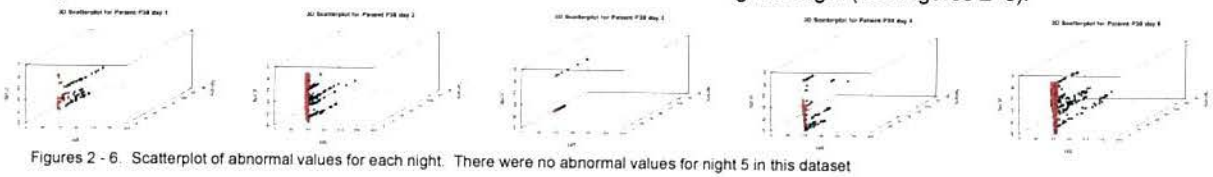


Figure 1. Scatterplot of abnormal values (SpO2 < 85, HR >95 or < 50, and activity) for all nights

There were differences in the coefficient of variation across all nights, high (>= 0.10 to 0.14) for 10 patients, moderate (>=0.05 to < 0.10) for 23 patients, and low (0.01 to < 0.05) for 4 patients.

For each patient there was significant variation in blood oxygen saturation and heart rate across nights. Eighty-two percent (28 of 37) patients experienced blood oxygen saturation values less than 85% with heart rates greater than 95 or less than 50 beats per minute. We masked the normal values by plotting only low blood oxygen saturation against high and low heart rate values and activity, to better demonstrate relationships between abnormal values. Figure 1 shows an example of extreme variation in blood oxygen saturation and heart rate for one representative patient dataset. Activity is plotted on a spectrum anchored with lowest activity being brightest and highest activity being darkest points. Further, plotting each night individually shows marked variation in the pattern of the abnormal values from night to night (see Figures 2–6).



Figures 2 - 6. Scatterplot of abnormal values for each night. There were no abnormal values for night 5 in this dataset

There were differences in the coefficient of variation across all nights, high (>0.03) for 6 patients, moderate (<=0.02 to >=0.03) for 26 patients, and low (<0.02) for 5 patients. For all patients, the mean heart rate was 72.4 (SD, 12.1) beats per minute. There was low variation in heart rate, mean coefficient of variability was 0.08 (SD, 0.03). The mean minimum heart rate was 37 (SD, 13) and the mean maximum heart rate was 180 (SD, 68) beats per minute. Almost all of the patients 92% (34 of 37) experienced heart rates less than 60 beats per minute. Almost all patients 89% (33 of 37) experienced heart rates greater than 100 beats per minute. Additionally, almost half the patients, 49% (18 of 37), experienced maximum heart rates greater than 200 bpm.

Discussion

Patients are willing able to collect important clinical information between clinic visits. These data can be arranged in a way that is useful to clinicians. Visually organizing and presenting these patient collected data provide information that is not readily apparent when viewing all the data together. Patients with heart failure display extreme deviation in blood oxygen saturation and heart rate overnight. Moreover, there is variation in these extreme deviations from night to night. This information may be helpful to clinicians in formulating individually tailored clinical management plans for patients with heart failure.

Severe and Significant Variation in Overnight Heart Rate and Blood Oxygen Saturation in Patients with Heart Failure

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Abstract

Background

Accurate between-visit information is essential to the management of patients with chronic disease, such as heart failure. Information provided by patients during interval history is often inaccurate and incomplete; yet, it is this information upon which clinician base treatment decisions. Moreover, short duration studies, as with polysomnography, are unable to capture night-to-night variability that patients experience. Patient-facing electronic devices are capable of collecting, storing and transmitting data that would be otherwise inaccessible. We hypothesize that patients with heart failure experience severe and significant night-to-night differences in blood oxygen saturation and heart rate.

Methods

We recruited 37 patients with heart failure during routine clinic visits and asked them to wear a pulse oximeter and actigraph overnight for six nights and return the equipment 7 days later. We describe nocturnal blood oxygen saturation, heart rate and activity, and we conducted one-way analysis of variance crossing blood oxygen saturation and heart rate across nights.

Results

The average age of the participants was 67.2 (SD, 12.6), 26 (70%) were male, 24 (65%) were African-American. In terms of NYHC: I, 11 (30%); II, 20 (54%); and III, 6 (16%). Two patients were prescribed nocturnal oxygen therapy, and eight patients were prescribed CPAP at night.

Mean oxygen saturation across all patient nights was 92.4% (SD, 3.5), with differences in the coefficient of variation across all nights, high (>0.03) for 6 patients, moderate (<=0.02 to >=0.03) for 26 patients, and low (<0.02) for 5 patients. The mean coefficient of variability of 0.03 (SD, 0.01). Approximately 41%, (15 of 37) patients experienced oxygen saturations below 70%, with approximately 16% (6 of 37) patients experienced oxygen saturations below 60%.

Mean heart rate was 72.4 (SD, 12.1) beats per minute with differences in the coefficient of variation across all nights, high (>= 0.10 to 0.14) for 10 patients, moderate (>=0.05 to < 0.10) for 23 patients, and low (0.01 to < 0.05) for 4 patients. The mean minimum and maximum heart rates were 37 (SD, 13) and 180 (SD, 68) beats per minute, respectively. Almost all of the patients 92% (34 of 37) experienced episodes of heart rate less than 60 beats per minute, and 89% (33 of 37) experienced episodes of heart rates greater than 100 beats per minute.

There was significant variation in blood oxygen saturation and heart rate across nights; 82% (28 of 37) patients experienced blood oxygen saturation values less than 85% with heart rates greater than 95 or less than 50 beats per minute.

Conclusion

Patients are willing able to collect important clinical information between clinic visits that can be arranged in a way that is useable to clinicians. Patients with heart failure display extreme deviation in blood oxygen saturation and heart rate overnight, some with extreme variation from night to night. Collecting and processing data in this way provides clinicians with information that is otherwise inaccessible; yet, is indispensable for formulate individually tailored clinical management plans for patients with heart failure with such extreme and variable states.

Volunteer Name: _____

SAN ANTONIO MILITARY MEDICAL CENTER/WILFORD HALL AMBULATORY SURGICAL CENTER

INFORMED CONSENT DOCUMENT

The Effects of Balloon Sinuplasty on Barometric Pressure/"Sinus" Headaches
FWH20150103H

This consent document is written in second person for those individuals completing it for their own participation in the study. The language should be considered to refer to the research subject or when a guardian or legal representative is completing the form on the research subject's behalf. Therefore, this informed consent document will serve for adult, or surrogate/substitute consent).

INFORMATION ABOUT THIS CONSENT FORM:
You may be eligible to take part in a research study. This form gives you important information about the study. You may be asked to sign in more than one place in this document.

Please take time to review this information carefully. You should talk to the researchers about the study and ask them any questions you may have for them. You may also wish to talk to others (for example, your friends, family, or a doctor) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand the procedures of the study and what the study is about, including the risks and possible benefits to you. If you are taking part in another research study, please tell the researchers or study staff.

VOLUNTARY PARTICIPATION:
You do not have to participate in the study if you don't want to participate. You may also leave the study at any time. If significant new findings develop during the course of this study that may relate to your decision to continue to participate in the study, you will be informed.

If you choose not to participate in this research study or leave before it is finished, your decision will not affect your eligibility for care or any other benefits to which you are entitled.

PRINCIPAL INVESTIGATOR:
The Principal Investigator (PI) is the researcher directing this study and is responsible for protecting your rights, safety and welfare as a participant in the research. The PI for this study is Maj Adrienne M. Laury, MD, Department of Otolaryngology, SAMMC.

PURPOSE OF THIS STUDY (Why is this study being done?)**:**
Sinus headaches/Barometric pressure headaches are a relatively common phenomenon with no current

validated treatment options. This is defined as pressure or pain overlying the sinuses which increases with changes in barometric pressure or weather changes, with no evidence of any disease pathology on sinus CT scan. No studies, to date, have identified effective treatments for this pathophysiology. The purpose of this study is to see if an inflated balloon can be used to open the entryways into your sinuses and see if that improves your headache severity or duration. We will also be looking at the effect of this dilation procedure of your sinuses on your snoring, sleep apnea, and medication use for headache pain, as applicable.

You are being asked to consider participation in a research study of balloon sinuplasty (eg. Dilation of the sinuses) on barometric pressure/sinus headaches. Currently, there is no standard of care or validated, effective treatment for this pathophysiology. Therefore this study is hoping to find an effective treatment. The purpose of this study is to identify if balloon sinuplasty can reduce the severity and frequency of headaches or change the use of medication for sinus headache. We are also looking to see if snoring or apnea/hypopnea index (AHI) values are altered by this technique. AHI is used to determine the severity of sleep apnea. Patient's participation in this arm of the study is optional.

You have been selected to participate in this study because you meet the initial study criteria for having barometric/sinus pressure headaches and do not meet the diagnostic criteria for migraine, cluster (type of headache), or medication over-use headache. Since there is no validated, effective treatment for this disease process, we are seeking to determine if balloon sinuplasty can improve the symptoms of this disease condition.

This study will enroll approximately _50__ subjects over a period of 2 years, with approximately 25 at BAMC and 25 at WHASC.

This study will help find out what effects, good and/or bad, balloon sinuplasty procedure will have on people with sinus pressure/barometric pressure headache. The safety of this procedure in humans has been tested in prior research studies; however, some side effects may not yet be known.

PROCEDURES:

If you decide to take part in this research study, you will be asked to sign this consent form.

During your participation in this study, you will be asked to make approximately _3___follow-up visits with Dr. Laury, the Principal Investigator (PI) or study staff. It may be necessary for you to return to the Otolaryngology Clinic at WHASC/SAMMC at 2 weeks, 3 months, and 6 months after your initial procedure. These visits would be held in conjunction with visits the subject would be making as part of routine care.

Screening – exams, tests, and/or procedures may be done after you sign this consent to participate. This screening is done to find out if you can continue in the study (screening procedures). We may be able to use the results of exams, tests, and/or procedures you completed before enrolling in this study. You will be told which results we will obtain and which procedures will not have to be repeated. Any procedure described below as "standard care" would be done even if you do not take part in this research study.

- You must have completed a sinus CTS scan within the past year, which is clear of sinus infection in

the area of reported sinus pain, in order to be considered for this study

Assignment to Study Groups –

With randomization:

When it is determined that you are eligible for the study, you will be assigned by chance (like flipping a coin)to one of 2 study groups.

- *Balloon sinuplasty*
- *Nasal cavity dilation*

You will not know whether you are undergoing the balloon sinuplasty or nasal cavity dilation. The researchers will know which procedure you are receiving.

Study Procedures - as a research participant, you will undergo the following study-related procedures after signing this informed consent document:

- After meeting inclusion criteria which will be determined by the resident or staff in the Otolaryngology clinic, you will be asked to fill out four questionnaires . This will take you approximately 20-25 minutes of your time.
- You will be offered the opportunity to participate in a pre-treatment and post-treatment sleep study (the sleep study will be optional).
- You will be asked to maintain a medication log for recording what medications you use for your headaches over at least a 3 week period prior to your sinus procedure.
- You will then come to the clinic for your procedure. Your nose will be numbed and headphones will be placed on your ears. You will then undergo either balloon dilation of affected sinuses (based on where you pain is located) or nasal cavity dilation. In this procedure, the balloon is placed into the sinus ostia and dilated to 6-7mm in diameter using water to fill the balloon. The balloon is then deflated and removed from the sinus ostia. For the nasal dilation, the balloon will be placed in the middle meatus and inflated to 6-7mm in diameter and then deflated and removed.
- You will be monitored in the clinic for 10 minutes following your procedure to ensure no complications result.
- You will return to clinic in 2 weeks following your sinus procedure and repeat the four questionnaires again. If you completed a pre-op sleep study, your post-op sleep study will be ordered at this visit. You will ideally undergo this sleep study between 4-12 weeks following your initial sinus procedure.
- You will continue maintaining your medication log at home.
- You will return to clinic at 3 months post-procedure and once again complete the four questionnaires. You will continue maintaining your medication log at home.
- You will return to clinic at 6 months post-procedure and once again complete the four questionnaires. You will turn-in your medication log to the Principal Investigator or to a research team member.

RISKS OR DISCOMFORTS:

- Likely: Pain/Discomfort
- Unlikely: Bleeding
- Unlikely but serious: Orbital injury/injury to the brain
- Likely: Recurrence of pain

Everyone taking part in this study will be watched carefully for any side effects. However, the study doctors don't know all the side effects that may happen. Be sure to tell your study doctor immediately, about any side effect that you have while taking part in the study.

Are there risks if you also participate in other research studies?
Being in more than one research study at the same time, may increase the risk to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers.

There may also be unforeseen risks associated with this or any research study.

WITHDRAWAL FROM THE STUDY:
If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care and you will not be penalized or lose any benefits to which you would otherwise be entitled.

ARE THERE RISKS RELATED TO WITHDRAWING FROM THE STUDY?

If you decide to withdraw from this study early, please discuss your decision with the principal investigator. The researcher may ask you to complete study withdrawal procedures at a final study visit. There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

BENEFITS:
The possible benefit of your participating in this study may include improvement in your headache by a decrease in frequency or severity as well as a possible decrease in your medication useage for headache pain. Benefits may also include a decrease in your snoring or a decrease in your obstructive sleep apnea, if this is a predisposing condition. However, direct benefit cannot be guaranteed from your participation in this study.

COSTS: Will taking part in this study cost anything?
The investigators have designed this study so there is no cost to you as a study participant other than what it will cost you to travel to the research appointments."

The extent of medical care provided on this research protocol is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries. Your entitlement to medical and dental care is governed by federal laws and regulations.

PAYMENT (COMPENSATION):
You will not receive any compensation (payment) for participating in this study.

POTENTIALLY BENEFICIAL ALTERNATIVES TO STUDY PROCEDURES OR INTERVENTIONS:
Alternatives to receiving balloon sinuplasty as part of this research are not available as there are no other standard of care treatment options that have been validated by research studies.

Choosing not to participate in this study is also an alternative.

CONFIDENTIALITY OF RECORDS OF STUDY PARTICIPATION:
Records of your participation in this study may only be disclosed in accordance with federal law, including the Federal Privacy Act, 5 U.S.C. § 552a, the Health Insurance Portability & Accountability Act of 1996, Public Law 104-109 (also known as HIPAA), and their implementing regulations. DD Form 2005, Privacy Act Statement- Military Health Records, contains the Privacy Act Statement for the records.

By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

Your records may be reviewed by the U.S. Food & Drug Administration (FDA), the Air Force, the DoD, other government agencies that oversee human research, and the 59 MDW Institutional Review Board.

A copy of this consent will be stored by the investigator in a locked cabinet in a locked room, as part of your research record. Information collected on this study about you that represents standard care and results of tests run by accredited laboratories will be placed in your medical record Your medical record will be annotated to reflect you are participating in a research study for each visit because this study involves an intervention that is for research purposes only.) All coded identifying information and de-identified research information about you collected on this study will be kept separately in an electronic database, which will be double password-protected, firewall-protected and access-restricted to people involved in this study. A lay definitioin of firewall is: a firewall is a protection or varrier within a computer to protect the information from being viewed by unauthorized people. As soon as possible, any link between your identity and the research information will be destroyed which means research information about you will be permanently de-identified. The research information collected about you for this study will not be used for any additional research activity beyond what you have approved by signing this consent.

The study staff advises that you protect your copy of the informed consent document. A breach of confidentiality could occur if you inadvertently lose this document or allow others to view the document. In the unlikely event that you experience a loss of confidentiality, the study staff will take appropriate

action to assist you.

Complete confidentiality cannot be promised, particularly for military personnel, because information regarding potential UCMJ violations or concerns regarding fitness for duty may be reported to appropriate medical, law enforcement, or command authorities.

ENTITLEMENT TO CARE:

The researchers have taken steps to minimize the known or expected risks. However, you may still experience problems or side effects, even though the researchers are careful to avoid them. In the event of injury resulting from this study, the extent of medical care provided is limited and will be within the scope authorized for Department of Defense (DoD) health care beneficiaries.

Your entitlement to medical and dental care and/or compensation in the event of injury is governed by federal laws and regulations.

If you believe that you have been harmed, notify the researchers as soon as possible. You may also need to tell your regular doctors.

If you have questions about your rights as a research subject or if you believe you have received a research-related injury, you may also contact the Director, Clinical Research Division, (210) 292-7069.

CONTACT INFORMATION:

Principal Investigator (PI):
The principal investigator and alternate member of research staff will be available to answer any questions concerning procedures throughout this study.

Principal Investigator: Adrienne M Laury MD Phone: (210) 916-2367
Alternate contact: Associate Investigator: Erik Weitzel MD Phone: (210) 916-4080

Institutional Review Board (IRB):
The 59 MDW Institutional Review Board (IRB), the hospital committee that reviews research on human subjects, will answer any questions about your rights as a research subject, and take any concerns, comments or complaints you may wish to offer at (210) 292-4783. You can contact the IRB by calling the Chairperson of the 50 MDW IRB at (210) 916-8251, or by mail to IRB at 59th MDW/SGVUS, 2200 Bergquist Dr, Lackland Air Force Base, Texas 78236.

All oral and written information and discussions about this study have been in English, a language in which you are fluent.

If you agree to participate in this research study, please sign this section. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.
- Your questions have been answered to your satisfaction.
- Your consent to participate in this study is given on a voluntary basis.

A signed copy of this form has been given to you.

_____ _____

VOLUNTEER'S SIGNATURE **DATE**

_____

VOLUNTEER'S PRINTED NAME

_____

VOLUNTEER'S ADDRESS (street, city, state, zip)

_____ _____ (___)____-_____

ADVISING INVESTIGATOR'S SIGNATURE **DATE** **PHONE#**

_____

PRINTED NAME OF ADVISING INVESTIGATOR

_____ _____

WITNESS' SIGNATURE **DATE**
(Must witness ALL signatures)

_____

PRINTED NAME OF WITNESS

For Protocol Office Use Only:
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Version: 0514